AMENDED IN ASSEMBLY AUGUST 25, 2005

AMENDED IN ASSEMBLY JULY 6, 2005

AMENDED IN ASSEMBLY JUNE 15, 2005

AMENDED IN SENATE APRIL 26, 2005

AMENDED IN SENATE MARCH 29, 2005

# SENATE BILL No. 484

**Introduced by Senator Migden**
**(Coauthors: Senators ~~Alquist and Ortiz~~ *Alquist, Kuehl, Ortiz, and Torlakson*)**
(Coauthors: Assembly Members Berg, ~~Goldberg,~~ *Chan, Evans, Goldberg, Karnette, Lieber, Montanez,* and Nation)

February 18, 2005

An act to add Article 3.5 (commencing with Section 111791) to Chapter 7 of Part 5 of Division 104 of the Health and Safety Code, relating to cosmetics.

LEGISLATIVE COUNSEL'S DIGEST

SB 484, as amended, Migden. Cosmetics: chronic health effects.

The existing Sherman Food, Drug, and Cosmetic Law requires the State Department of Health Services to regulate the packaging, labeling, and advertising of food, drugs, and cosmetics. The law prohibits a person from manufacturing, selling, delivering, holding, offering for sale, or receiving in commerce any cosmetic that is adulterated, and prohibits a person from adulterating any cosmetic. The law also prohibits a person from manufacturing or selling any cosmetic that is misbranded. A violation of these provisions is a crime.

This bill would establish the California Safe Cosmetics Act of 2005. The bill, commencing January 1, 2007, would require the manufacturer of any cosmetic product subject to regulation by the federal Food and Drug Administration that is sold in the state, with certain exceptions, on a schedule *and in electronic or other format, as* determined by the Division of Environmental and Occupational Disease Control within the department, to provide the division with a list of its cosmetic products that*, as of the date of submission,* are sold in the state and ~~to identify by product any ingredient that contains~~ *contain any ingredient that is* a chemical identified as causing cancer or reproductive toxicity. Since a violation of the provisions applicable to the packaging, labeling, and advertising of food, drugs, and cosmetics is a crime, this bill would impose a state-mandated local program.

The bill would authorize the division to conduct an investigation of cosmetic products that contain chemicals identified as causing cancer or reproductive toxicity or other ingredients of concern to the division. The bill would authorize the division to require manufacturers of products subject to investigation to submit relevant health effects data and studies and other information as requested by the division. The bill would require the division to establish reasonable deadlines for the submittal of that information and would make failure by a manufacturer to submit the information a crime, thereby imposing a state-mandated local program. If the division determines that an ingredient in a cosmetic product is potentially toxic, the bill would require the division to immediately refer the results of its investigation to the Division of Occupational Safety and Health in the Department of Industrial Relations and would require the Division of Occupational Safety and Health, within 180 days after it receives the results, to develop and present one or more proposed occupational health standards to the Occupational Safety and Health Standards Board in the Department of Industrial Relations, unless the Division of Occupational Safety and Health affirmatively determines, in a written finding within 90 days, that a standard is not necessary to protect the health of an employee who has regular exposure to the hazard for the period of his or her working life.

The bill would authorize the division, as early as feasible within existing resources, to determine whether certain cosmetics have been adequately substantiated for safety, and if the cosmetic has, to determine if the cosmetic contains any ingredient that is not safe for

the specific use indicated on the product's label. If the division finds that a product has been adequately substantiated for safety despite containing an unsafe ingredient, the bill would require the division to refer its findings to the Attorney General and the federal Food and Drug Administration for possible enforcement action.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:*

SECTION 1. The Legislature finds and declares all of the following:

(a) Independent testing in the United States and the European Union has determined that some cosmetic products contain substances known or suspected to cause cancer and reproductive toxicity that can harm the mother, fetus, and nursing children.

(b) Neither the federal Food and Drug Administration (FDA) nor the State Department of Health Services (DHS) require premarket safety testing, review, or approval of cosmetic products. According to the FDA, the regulatory requirements governing the sale of cosmetics are not as stringent as those that apply to other FDA-regulated products.

(c) Under the federal Food, Drug and Cosmetic Act (21 U.S.C. Sec. 301), cosmetics and their ingredients are not required to be approved before they are sold to the public and the FDA does not have the authority to require manufacturers to file health and safety data on cosmetic ingredients or to order a recall of a dangerous cosmetic product.

(d) Under the state Sherman Food, Drug, and Cosmetic Act, DHS has no authority to identify, review, or regulate ingredients in cosmetic products that may cause chronic health effects, such as cancer and reproductive toxicity.

(e) Cosmetic products are most heavily used by women of childbearing age, increasing the likelihood of exposing mothers,

fetuses, and nursing children to substances that can cause cancer and reproductive toxicity.

(f) Beauty care workers, including cosmetologists and manicurists, are most exposed to the potentially harmful effects of carcinogens and reproductive toxins in cosmetics. Cosmetologists and manicurists are dominated by women and minorities, particularly from Southeast Asia. In California, an estimated 80 percent of nail salons are operated by Vietnamese women.

(g) Federal law exempts chemicals used as fragrances or flavoring from being identified as ingredients on the labels of cosmetic products. Laboratory analyses of cosmetic products sold in California have found products that contain substances known to or likely to cause cancer or reproductive toxicity and not identified as an ingredient on the product's label. The law also does not require any ingredient labeling on cosmetic products sold for commercial use, thereby denying any information on ingredients to beauty care workers.

(h) The Division of Environmental and Occupational Disease Control in DHS conducts investigations of toxic materials in the workplace and analyzes data on workplace exposures to toxic materials. The Division of Occupational Safety and Health in the Department of Industrial Relations enforces occupational safety and health standards adopted by the Occupational Safety and Health Standards Board.

(i) Alternatives to substances that cause cancer or reproductive toxicity are readily available for use in cosmetic products. A number of manufacturers, including both small domestic producers and large multinational corporations, have eliminated substances that cause cancer or reproductive toxicity from their products.

(j) Given the presence of substances in cosmetic products that cause cancer and reproductive toxicity, the heavy use of these products by women of childbearing age, the significant exposure to these products in occupational settings such as nail and beauty salons, the adverse impacts of these substances on human health, the inadequate information about the presence of these substances in products or the extent of their impacts, and the availability of alternatives to the use of these substances, it is in the interest of the people of the State of California to take steps to

ensure that cosmetic products sold and used in the state can be used safely.

SEC. 2. Article 3.5 (commencing with Section 111791) is added to Chapter 7 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 3.5. Chronic Health Effects of Cosmetics

111791. This article shall be known, and may be cited, as the California Safe Cosmetics Act of 2005.

111791.5. For purposes of this article, the following terms have the following meanings:

(a) "Authoritative body" means any agency or formally organized program or group recognized pursuant to Section 12306 of Title 22 of the California Code of Regulations as being authoritative for the purpose of identifying chemicals that cause cancer or reproductive toxicity.

(b) "Chemical identified as causing cancer or reproductive toxicity" means a chemical identified pursuant to Section 25249.8 or identified by an authoritative body as any of the following:

(1) A substance listed as known or reasonably anticipated to be a human carcinogen in a National Toxicology Report on carcinogens.

(2) A substance given an overall carcinogenicity evaluation of Group 1, Group 2A, or Group 2B by the International Agency for Research on Cancer.

(3) A substance identified as a Group A, Group B1, or Group B2 carcinogen, or as a known or likely carcinogen by the United States Environmental Protection Agency.

~~(4)~~

*(4)* A substance identified as having some or clear evidence of adverse developmental, male reproductive, or female reproductive toxicity effects in a report by an expert panel of the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction.

(c) "Division" means the Division of Environmental and Occupational Disease Control within the State Department of Health Services.

(d) "Ingredient" has the same meaning as that term is defined in subdivision (e) of Section 700.3 of Part 700 of Chapter 1 of Title 21 of the Code of Federal Regulations and does not include any incidental ingredient as defined in subdivision (*l*) of Section 701.3 of Part 701 of Chapter 1 of Title 21 of the Code of Federal Regulations.

*(e) "Manufacturer" means any person whose name appears on the label of a cosmetic product pursuant to the requirements of Section 701.12 of Title 21 of the Code of Federal Regulations.*

111792. (a) Commencing January 1, 2007, the manufacturer of any cosmetic product subject to regulation by the federal Food and Drug Administration that is sold in this state shall, on a schedule *and in electronic or other format, as* determined by the division, provide the division with a complete and accurate list of its cosmetic products that*, as of the date of submission,* are sold ~~in the state as of the date of submission and shall identify by product~~ *in the state and that contain* any ingredient that is a chemical identified as causing cancer or reproductive toxicity, including any chemical that meets either of the following conditions:

(1) A chemical contained in the product for purposes of fragrance or flavoring.

(2) A chemical identified by the phrase "and other ingredients" and determined to be a trade secret pursuant to the procedure established in Part 20 and Section 720.8 of Part 720 of Title 21 of the Code of Federal Regulations. Any ingredient identified pursuant to this paragraph shall be considered to be a trade secret and shall be treated by the division in a manner consistent with the requirements of Part 20 and Part 720 of Title 21 of the Code of Federal Regulations. Any ingredients considered to be a trade secret shall not be subject to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code) for the purposes of this section.

(b) Any information submitted pursuant to subdivision (a) shall identify each chemical both by name and Chemical Abstract Service number *and shall specify the product or products in which the chemical is contained*.

(c) If an ingredient identified pursuant to this section subsequently is removed from the product in which it was

contained, is removed from the list of chemicals known to cause cancer or reproductive toxicity published under Section 25249.8, or is no longer a chemical identified as causing cancer or reproductive toxicity by an authoritative body, the manufacturer of the product containing the ingredient shall submit the new information to the division. Upon receipt of new information, the division, after verifying the accuracy of that information, shall revise the manufacturer's information on record with the division to reflect the new information. The manufacturer shall not be under obligation to submit subsequent information on the presence of the ingredient in the product unless subsequent changes require submittal of the information.

(d) This section shall not apply to any manufacturer of cosmetic products with annual aggregate sales of cosmetic products, both within and outside of California, of less than one million dollars ($1,000,000), based on the manufacturer's most recent tax year filing.

111792.5. (a) In order to determine potential health effects of exposure to ingredients in cosmetics sold in the state, the division may conduct an investigation of one or more cosmetic products that contain chemicals identified as causing cancer or reproductive toxicity or other ingredients of concern to the division.

(b) An investigation conducted pursuant to subdivision (a) may include, but not be limited to, a review of available health effects data and studies, worksite health hazard evaluations, epidemiological studies to determine the health effects of exposures to chemicals in various subpopulations, and exposure assessments to determine total exposures to individuals in various settings.

(c) If an investigation is conducted pursuant to subdivision (a), the manufacturer of any product subject to the investigation may submit relevant health effects data and studies to the division.

(d) In order to further the purposes of an investigation, the division may require manufacturers of products subject to the investigation to submit to the division relevant health effects data and studies available to the manufacturer and other available information as requested by the division, including, but not limited to, the concentration of the chemical in the product, the amount by volume or weight of the product that comprises the

average daily application or use, and sales and use data necessary to determine where the product is used in the occupational setting.

(e) The division shall establish reasonable deadlines for the submittal of information required pursuant to subdivision (d). Failure by a manufacturer to submit the information in compliance with the requirements of the division shall constitute a violation of this part.

111793. (a) If the division determines pursuant to an investigation that an ingredient in a cosmetic product is potentially toxic at the concentrations present in the product or under the conditions used, the division shall immediately refer the results of its investigation to the Division of Occupational Safety and Health in the Department of Industrial Relations and the Office of Environmental Health Hazard Assessment.

(b) Within 180 days after it receives the results of an investigation pursuant to subdivision (b), the Division of Occupational Safety and Health shall, pursuant to Section 147.1 of the Labor Code, develop and present one or more proposed occupational health standards to the Occupational Safety and Health Standards Board in the Department of Industrial Relations, unless the Division of Occupational Safety and Health affirmatively determines, in a written finding within 90 days, that a standard is not necessary to protect the health of an employee who has regular exposure to the hazard for the period of his or her working life. The written finding shall identify the reasons for determining the standard is not necessary and the factual basis for the finding.

111793.5. (a) The Legislature finds and declares the following:

(1) The Cosmetic Ingredient Review (CIR) panel is a nongovernmental body established and funded by the cosmetics industry to review the safety of cosmetic ingredients.

(2) According to a 2004 analysis of the 2003 CIR Compendium by the Environmental Working Group, 54 cosmetic products violate the CIR's own safe use recommendations to manufacturers by containing an ingredient that the CIR has found is not safe for the specific use indicated on the product's label.

(3) Federal regulations (21 C.F.R. 740.10) require every ingredient in a cosmetic product and every finished cosmetic

product to be adequately substantiated for safety prior to marketing, and state that any ingredient or product whose safety has not been adequately substantiated prior to marketing is misbranded unless it displays a warning statement declaring, "The safety of this product has not been determined."

(b) The division may, as early as feasible within existing resources, determine whether the products identified in paragraph (2) of subdivision (a) have been adequately substantiated for safety pursuant to Section 740.10 of Title 21 of the Code of Federal Regulations. For any product adequately substantiated for safety, the division shall determine if the product contains any ingredient that the CIR has found is not safe for the specific use indicated on the product's label.

(c) If the division finds that a product has been adequately substantiated for safety despite containing an ingredient that the CIR has found is not safe for the specific use indicated on the product's label, the division shall refer its findings to the Attorney General and the federal Food and Drug Administration for possible enforcement action pursuant to this part and the federal Food, Drug and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O